

Applicant: Ching-Fen Hsiao et al.
Serial No.: 10/784,499
Filed: February 23, 2004
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Remarks

Claims 1-5 are pending in the subject application. By this Amendment, applicants have amended claim 1. Applicants maintain that the amendment to the claim 1 raises no issue of new matter and is fully supported by the specification as filed. Support for the amendment to claim 1 may be found, *inter alia*, in the specification, as originally filed, on page 4, lines 22-23 and in original claim 1. Accordingly, applicants respectfully request entry of this Amendment. Upon entry of this Amendment, claims 1-5 will be pending and under examination.

Claims Rejected Under 37 C.F.R §102(e)

In the November 4, 2004 Office Action, the Examiner rejected claims 1-5 as allegedly anticipated by Vaghefi et al., US 2003/0157326 A1.

In response, applicants respectfully traverse the Examiner's rejection. However, in order to expedite prosecution, but without conceding the correctness of the Examiner's position, applicants have hereinabove amended claim 1. As amended, claim 1 recites that the formulation comprises "0.03% to 3% by weight tamsulosin." Applicants note that Vaghefi et al. do not teach such a formulation. Applicants further note that Vaghefi et al. only discuss bioactive compound content of between 10 and 45%, or 20-35% (see paragraph [0066]).

Thus, applicants maintain that Vaghefi et al. do not teach all the elements of applicants claimed invention. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this rejection.

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Claims Rejected under 37 C.F.R §103(a)

The Examiner rejected claims 1-5 as allegedly obvious over Fukui et al., US 4,772,475.

In response, applicants respectfully traverse the Examiner's rejection. However, in order to expedite prosecution, but without conceding the correctness of the Examiner's position, applicants have hereinabove amended claim 1. As amended, claim 1 recites that the formulation comprises "0.03% to 3% by weight tamsulosin." Applicants note that Fukui et al. do not teach such a formulation.

Applicants further note that the composition discussed in Fukui et al. gives a different plasma concentration profile than the claimed formulation. Specifically, applicants note the different shapes of the profiles set forth in Figure 1 of applicants' specification compared with Figures 1-3 of Fukui et al. show that the two formulations are distinct in their activity. In addition, the background of applicants' specification at page 1, lines 11 to 24, specifically points out the need for a formulation acts differently to the formulation described in Fukui et al. and this need is what applicants' invention addresses.

Thus, applicants maintain that Fukui et al. do not teach all the elements of applicants claimed invention. In addition, the claimed formulation is not obvious over Fukui et al. in light of the different release profiles observed. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this rejection.

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Additional Remarks

Claims 1 to 5 are rejected under 35 U.S.C. §102(e) as being anticipated by Vaghefi et al. and are rejected under 35 U.S.C. §103(a) as being obvious over Fukui et al. Applicants are herewith submitting declarations to further show the differences between the currently claimed invention and the formulations discussed in the citations. These declarations are submitted in compliance with provisions of 37 C.F.R. §1.132.

With regard to claims 1 to 5 being anticipated by Vaghefi et al., Declaration A (**Exhibit A**) (7 pages in total) shows the physical differences between the formulation of Vaghefi et al. and the present invention by scanning electron microscopy (SEM). As shown in the SEM photographs (Figures 1 and 2) attached to Declaration A, the components of the microsphere of the present invention are well mixed and are continuously distributed. Specifically, the rough outer surface of the microsphere of the present application (see Figs. 1 and 2) of Declaration A) differs from the smooth outer surface of Vaghefi, et al., see Figs. 1 and 2. The rough outer surface indicates that all components including the active ingredient and excipients of the microsphere are uniformly mixed, while the smooth outer surface of the microsphere of Vaghefi et al. indicates that no active ingredient and excipients are present in the outer surface of the microsphere.

With regard to Claims 1 to 5 being rejected under 35 U.S.C. §103(a) as being obvious over Fukui et al., Declaration B (**Exhibit B**) (4 pages in total) shows the material difference between Fukui et al. and the present invention by the table shown

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in the Declaration. An excerpt from the "*Handbook Pharmaceuticals Excipients*" is attached to Declaration B and this shows that an elevated temperature will cause acrylic acid polymers to become glue-like during granulation. The glue-like condition causes technical difficulties with the granulation. As stated in the Declaration, the lower concentration of aqueous controlling agent in the present invention was useful in the prevention of the glue-like condition during granulation. The table shows the lower concentration of aqueous controlling agent would not cause the glue-like condition during granulation.

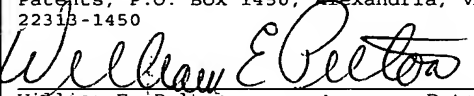
If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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